

## General

### Guideline Title

Sentinel node biopsy in primary cutaneous melanoma.

### Bibliographic Source(s)

Alberta Provincial Cutaneous Tumour Team. Sentinel node biopsy in primary cutaneous melanoma. Edmonton (Alberta): CancerControl Alberta; 2014 Feb. 13 p. (Clinical practice guideline; no. CU-011). [75 references]

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Alberta Cutaneous Tumour Team. Regional node dissection in primary cutaneous melanoma. Edmonton (Alberta): Alberta Health Services, Cancer Care; 2011 Feb. 11 p. (Clinical practice guideline; no. CU-011). [59 references]

## Recommendations

### Major Recommendations

For American Joint Committee on Cancer melanoma staging, please refer to the Appendix in the original guideline document.

An initial biopsy should first be performed according to recommendations outlined in the National Guideline Clearinghouse (NGC) summary of the CancerControl Alberta guideline [Biopsy of a suspicious pigmented lesion](#) .

1. For the purposes of staging, rationale for sentinel node biopsy (SLNB) includes the following (Australian Cancer Network Melanoma Guidelines Revision Working Party, 2008; Scottish Intercollegiate Guidelines Network [SIGN], 2003; Dummer, Hauschild, & Pentheroudakis, 2009; Chao et al., 2003; McMasters et al., 2001; Kruper et al., 2006; Scoggins et al., 2010):

- Primary melanoma >1.0 mm thick with any characteristic
- Primary melanoma >0.75 mm thick with mitotic rate  $\geq 1$  per  $\text{mm}^2$

Desmoplastic melanomas and pigmented epithelial melanocytomas can be discussed.

2. The contraindications for SLNB are as follows (Filippakis & Zografos, 2007; Lloyd et al., 2004):
  - Absolute contraindications: clinically positive (N1) axillary lymphadenopathy and positive fine-needle aspiration (FNA) cytology and/or core biopsy of palpable lymph nodes.
  - Relative contraindications (due to the disruption of the lymphatics): Prior wide excision of the primary tumour with rotation flap, prior extensive surgery (e.g., dissection of the neck), previous radiation to the head and the neck, allergy to blue dye and radiocolloid. While SLNB is not contraindicated in pregnancy, it should be noted that vital dyes have not been proven safe for use during

pregnancy. Radiocolloid should be used alone if SLNB is undertaken (Schwartz et al., 2002; Lyman et al., 2005; Chakera et al., 2009).

3. The treating centre and clinician must be experienced in SLNB.
4. In accordance with the College of American Pathologists' Protocol for the Examination of Specimens from Patients with Melanoma of the Skin (College of American Pathologists, 2011), pathological examination of the sentinel node should include:
  - Review of sentinel node specimens as multiple permanent sections examined by hematoxylin and eosin (H&E), and immunohistochemical staining for markers (i.e., S-100, HMB-45, MART-1, Melan-A)
  - Reporting of the following elements:
    - Number of sentinel nodes examined (total number of nodes examined: sentinel and non-sentinel)
    - Number of lymph nodes with metastases
    - Extranodal tumour extension (present, not identified, indeterminate)
    - Size of largest metastatic focus (mm, for sentinel node)
    - Location of metastatic tumour (subcapsular, intramedullary, subcapsular and intramedullary, for sentinel node)
5. The indications for a therapeutic node dissection and recommended extent of dissection are (Australian Cancer Network Melanoma Guidelines Revision Working Party, 2008; Dummer, Hauschild, & Pentheroudakis, 2009; National Comprehensive Cancer Network, 2010; Garbe et al., 2008; American Society of Plastic Surgeons, 2007; Badgwell et al., 2007; Wong et al., 2006; Kingham et al., 2010; Thomas, 2009; Wong et al., 2012):
  - Positive sentinel node biopsy (i.e. any malignant cells in the lymph node, regardless of size, is considered positive) (Balch et al., 2009)
  - Evidence of metastatic nodal disease
  - A therapeutic node dissection includes full levels (I to III) clearance in the axilla.
  - A therapeutic neck dissection may include a superficial parotidectomy as clinically indicated.
  - For inguinal node metastases, clearance of the intra-pelvic iliac and obturator nodes should be considered when the staging investigation demonstrates evidence of involvement.
6. Use of FNA biopsy, with ultrasound (US) or radiological guidance when required, is recommended for the identification of positive lymph nodes in patients suspected of having lymph node *metastasis* from cutaneous melanoma (Australian Cancer Network Melanoma Guidelines Revision Working Party, 2008; Voit et al., 2009).
  - The use of US examination alone is more accurate than palpation for the detection of lymph node metastases, as metastases >4.5 mm in size can be detected. However, SLNB is superior to US alone in the detection of occult regional lymph node metastases (Australian Cancer Network Melanoma Guidelines Revision Working Party, 2008; SIGN, 2003).
  - Note: The sensitivity of US-guided FNA biopsy was 65%; the specificity was 99%; the positive predictive value was 93% and the negative predictive value was 92%. Sensitivity varied with tumour size (40% for pT1a/b; 79% for pT4a/b) (Voit et al., 2009).
7. For follow-up, the routine use of US of the nodal basin is not recommended.
  - US may be used in conjunction with clinical examination only in the follow-up of patients with more advanced primary disease or following treatment of metastases (Australian Cancer Network Melanoma Guidelines Revision Working Party, 2008; Dummer, Hauschild, & Pentheroudakis, 2009).
  - Patients with a thin primary melanoma have only a small risk of relapse; imaging techniques are not necessary (SIGN, 2003; Dummer, Hauschild, & Pentheroudakis, 2009).

## Clinical Algorithm(s)

None provided

## Scope

## Disease/Condition(s)

Primary cutaneous melanoma

## Guideline Category

Evaluation

Management

Treatment

## Clinical Specialty

Dermatology

Oncology

Pathology

Radiation Oncology

Radiology

Surgery

## Intended Users

Clinical Laboratory Personnel

Physician Assistants

Physicians

## Guideline Objective(s)

To provide recommendations on some of the technical aspects of sentinel node biopsy in melanoma

## Target Population

Adults over the age of 18 years with malignant melanoma

Note: Different principles may apply to pediatric patients.

## Interventions and Practices Considered

1. Initial excisional biopsy of lesion
2. Sentinel node biopsy (SLNB)
3. Pathological examination of the sentinel node specimen
  - Multiple permanent sections, hematoxylin and eosin (H&E) staining, immunohistochemical staining for markers
  - Reporting of pathological examination
4. Therapeutic node dissection and extent of dissection as indicated
5. Fine-needle aspiration (FNA) biopsy with ultrasound (US) or radiological guidance
6. Routine use of US of nodal basin for follow up (not recommended except for advanced disease)

## Major Outcomes Considered

- Sensitivity, specificity, and positive and negative predictive value of diagnostic tests
- Incidence of positive sentinel node biopsy
- Nodal recurrence rate
- Disease-specific survival

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Research Questions

Specific research questions to be addressed by the guideline document were formulated by the guideline lead(s) and Knowledge Management (KM) Specialist using the PICO question format (Patient or Population, Intervention, Comparisons, Outcomes).

Guideline Questions

- What are indications and contraindications for sentinel node biopsy (SLNB)?
- How is the sentinel node examined pathologically?
- If the sentinel node is positive, what are the indications for a therapeutic node dissection and to what extent?
- What is the role of ultrasound-guided fine-needle aspiration in identifying positive lymph nodes?
- Should ultrasound be utilized before every SLNB?
- Is there a role for routine use of ultrasound for follow-up?

Search Strategy

The MEDLINE, EMBASE, and Cochrane databases were searched (1990 through May 2010) for clinical trials and meta-analyses. Search terms included: "fine needle aspiration" or "lymph node biopsy" or "lymph node dissection" or "complete lymph node dissection" AND "stage III melanoma" or "melanoma lymph node metastasis" with limits of Human and English language. A total of 25 clinical trials were identified by the search.

In addition, the National Guideline Clearinghouse and individual guideline organizations were searched for practice guidelines relevant to this topic. A total of eight original clinical practice guidelines were identified from the following organizations: the Australian Cancer Network, the National Comprehensive Cancer Network, the BC Cancer Agency, the European Dermatology Forum, the Scottish Intercollegiate Guidelines Network, the German Cancer Society, the American Society of Plastic Surgeons, and the European Society for Medical Oncology.

PubMed was again searched in 2013 for evidence on regional node dissection in cutaneous melanoma. The search term "melanoma" was used and results were limited to clinical trials, published through January 2013. Citations were hand-searched for studies pertaining to regional node dissection, resulting in a total of two prospective cohort studies and seven retrospective studies, as well as one updated clinical practice guideline from the American Society of Clinical Oncology. Following a review of the evidence by the Alberta Provincial Cutaneous Tumour Team, no changes to the recommendations were made.

Using the same search strategy, 4 relevant articles published between January 2013 and January 2014 were identified during the 2014 update.

## Number of Source Documents

Not stated

## Methods Used to Assess the Quality and Strength of the Evidence

Not stated

## Rating Scheme for the Strength of the Evidence

Not applicable

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Evidence was selected and reviewed by a working group comprised of members from the Alberta Provincial Cutaneous Tumour Team and a Knowledge Management (KM) Specialist from the Guideline Utilization Resource Unit (GURU). A detailed description of the methodology followed during the guideline development process can be found in the [Guideline Utilization Resource Unit Handbook](#)  (see the "Availability of Companion Documents" field).

Evidence Tables

Evidence tables containing the first author, year of publication, patient group/stage of disease, methodology, and main outcomes of interest are assembled using the studies identified in the literature search. Existing guidelines on the topic are assessed by the KM Specialist using portions of the Appraisal of Guidelines Research and Evaluation (AGREE) II instrument (<http://www.agreetrust.org> ) and those meeting the minimum requirements are included in the evidence document. Due to limited resources, GURU does not regularly employ the use of multiple reviewers to rank the level of evidence; rather, the methodology portion of the evidence table contains the pertinent information required for the reader to judge for himself the quality of the studies.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Formulating Recommendations

The working group members formulate the guideline recommendations based on the evidence synthesized by the Knowledge Management (KM) Specialist during the planning process, blended with expert clinical interpretation of the evidence. As detailed in the [Guideline Utilization Resource Unit Handbook](#)  (see the "Availability of Companion Documents" field), the working group members may decide to adopt the recommendations of another institution without any revisions, adapt the recommendations of another institution or institutions to better reflect local practices, or develop their own set of recommendations by adapting some, but not all, recommendations from different guidelines.

The degree to which a recommendation is based on expert opinion of the working group and/or the Provincial Tumour Team members is explicitly stated in the guideline recommendations. Similar to the American Society of Clinical Oncology (ASCO) methodology for formulating guideline recommendations, the Guideline Utilization Resource Unit (GURU) does not use formal rating schemes for describing the strength of the recommendations, but rather describes, in conventional and explicit language, the type and quality of the research and existing guidelines that were taken into consideration when formulating the recommendations.

For the current update, following a review of the evidence by the Alberta Provincial Cutaneous Tumour Team, minor changes were made to the recommendation on sentinel lymph node biopsy eligibility criteria and contraindications.

## Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

A formal cost analysis was not performed and published analyses were not reviewed.

## Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

This guideline was reviewed and endorsed by the Alberta Provincial Cutaneous Tumour Team.

When the draft guideline document has been completed, revised, and reviewed by the Knowledge Management (KM) Specialist and the working group members, it will be sent to all members of the Provincial Tumour Team for review and comment. This step ensures that those intended to use the guideline have the opportunity to review the document and identify potential difficulties for implementation before the guideline is finalized. Depending on the size of the document, and the number of people it is sent to for review, a deadline of one to two weeks will usually be given to submit any feedback. Ideally, this review will occur prior to the annual Provincial Tumour Team meeting, and a discussion of the proposed edits will take place at the meeting. The working group members will then make final revisions to the document based on the received feedback, as appropriate. Once the guideline is finalized, it will be officially endorsed by the Provincial Tumour Team Lead and the Executive Director of Provincial Tumour Programs.

## Evidence Supporting the Recommendations

### References Supporting the Recommendations

American Society of Plastic Surgeons. Evidence-based clinical practice guideline: treatment of cutaneous melanoma. Arlington Heights (IL): American Society of Plastic Surgeons; 2007 May. 14 p. [81 references]

Australian Cancer Network Melanoma Guidelines Revision Working Party. Clinical practice guidelines for the management of melanoma in Australia and New Zealand: treatment of primary melanoma. Wellington (NZ): The Cancer Council Australia, Australian Cancer Network, Sydney and New Zealand Guidelines Group; 2008. 73-7 p.

Badgwell B, Xing Y, Gershenwald JE, Lee JE, Mansfield PF, Ross MI, Cormier JN. Pelvic lymph node dissection is beneficial in subsets of patients with node-positive melanoma. *Ann Surg Oncol*. 2007 Oct;14(10):2867-75. [PubMed](#)

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Chakera AH, Hesse B, Burak Z, Ballinger JR, Britten A, Caraco C, Cochran AJ, Cook MG, Drzewiecki KT, Essner R, Even-Sapir E, Eggermont AM, Stopar TG, Ingvar C, Mihm MC Jr, McCarthy SW, Mozzillo N, Nieweg OE, Scolyer RA, Starz H, Thompson JF, Trifiro G, Viale G, Vidal-Sicart S, Uren R, Waddington W, Chiti A, Spatz A, Testori A, European Association of Nuclear Medicine-European Organisation for Research and. EANM-EORTC general recommendations for sentinel node diagnostics in melanoma. *Eur J Nucl Med Mol Imaging*. 2009 Oct;36(10):1713-42. [PubMed](#)

Chao C, Wong SL, Edwards MJ, Ross MI, Reintgen DS, Noyes RD, Stadelmann WK, Lentsch E, McMasters KM, Sunbelt Melanoma Trial Group. Sentinel lymph node biopsy for head and neck melanomas. *Ann Surg Oncol*. 2003 Jan-Feb;10(1):21-6. [PubMed](#)

College of American Pathologists (CAP). Protocol for the examination of specimens from patients with melanoma of the skin. Version 3.1.0.0. Northfield (IL): College of American Pathologists (CAP); 2011 Feb 1. 18 p.

Dummer R, Hauschild A, Pentheroudakis G. Cutaneous malignant melanoma: ESMO clinical recommendations for diagnosis, treatment and follow-up. *Ann Oncol*. 2009 May;20(Suppl 4):129-31. [18 references] [PubMed](#)

Filippakis GM, Zografos G. Contraindications of sentinel lymph node biopsy: are there any really. *World J Surg Oncol*. 2007;5:10. [106 references] [PubMed](#)

Garbe C, Terheyden P, Keilholz U, Kolbl O, Hauschild A. Treatment of melanoma. *Dtsch Arztebl Int*. 2008 Dec;105(49):845-51. [PubMed](#)

Kingham TP, Panageas KS, Ariyan CE, Busam KJ, Brady MS, Coit DG. Outcome of patients with a positive sentinel lymph node who do not undergo completion lymphadenectomy. *Ann Surg Oncol*. 2010 Feb;17(2):514-20. [PubMed](#)

Kruper LL, Spitz FR, Czerniecki BJ, Fraker DL, Blackwood-Chirchir A, Ming ME, Elder DE, Elenitsas R, Guerry D, Gimotty PA. Predicting sentinel node status in AJCC stage I/II primary cutaneous melanoma. *Cancer*. 2006 Nov 15;107(10):2436-45. [PubMed](#)

Lloyd MS, Topping A, Allan R, Powell B. Contraindications to sentinel lymph node biopsy in cutaneous malignant melanoma. *Br J Plast Surg*. 2004 Dec;57(8):725-7. [PubMed](#)

Lyman GH, Giuliano AE, Somerfield MR, Benson AB 3rd, Bodurka DC, Burstein HJ, Cochran AJ, Cody HS 3rd, Edge SB, Galper S, Hayman JA, Kim TY, Perkins CL, Podoloff DA, Sivasubramaniam VH, Turner RR, Wahl R, Weaver DL, Wolff AC, Winer EP. American Society of Clinical Oncology guideline recommendations for sentinel lymph node biopsy in early-stage breast cancer. *J Clin Oncol*. 2005 Oct 20;23(30):7703-20. [147 references] [PubMed](#)

McMasters KM, Wong SL, Edwards MJ, Ross MI, Chao C, Noyes RD, Viar V, Cerrito PB, Reintgen DS. Factors that predict the presence of sentinel lymph node metastasis in patients with melanoma. *Surgery*. 2001 Aug;130(2):151-6. [PubMed](#)

National Comprehensive Cancer Network (NCCN). Melanoma guidelines. Fort Washington (PA): National Comprehensive Cancer Network (NCCN); 2010.

Schwartz GF, Giuliano AE, Veronesi U, Consensus Conference Committee. Proceeding of the consensus conference of the role of sentinel lymph node biopsy in carcinoma of the breast April 19-22, 2001, Philadelphia, PA, USA. *Breast J*. 2002 May-Jun;8(3):124-38. [PubMed](#)

Scoggins CR, Martin RC, Ross MI, Edwards MJ, Reintgen DS, Urist MM, Gershenwald JE, Sussman JJ, Dirk Noyes R, Goydos JS, Beitsch PD, Ariyan S, Stromberg AJ, Hagendoorn LJ, McMasters KM. Factors associated with false-negative sentinel lymph node biopsy in melanoma patients. *Ann Surg Oncol*. 2010 Mar;17(3):709-17. [PubMed](#)

Scottish Intercollegiate Guidelines Network (SIGN). Cutaneous melanoma. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Jul. 50 p. (SIGN publication; no. 72). [277 references]

Thomas JM. Concerns relating to the conduct and statistical analysis of the Multicenter Selective Lymphadenectomy Trial (MSLT-1) in patients with melanoma. *J Plast Reconstr Aesthet Surg*. 2009 Apr;62(4):442-6. [13 references] [PubMed](#)



Voit CA, van Akkooi AC, Schafer-Hesterberg G, Schoengen A, Schmitz PI, Sterry W, Eggermont AM. Rotterdam Criteria for sentinel node (SN) tumor burden and the accuracy of ultrasound (US)-guided fine-needle aspiration cytology (FNAC): can US-guided FNAC replace SN staging in patients with melanoma. *J Clin Oncol*. 2009 Oct 20;27(30):4994-5000. [PubMed](#)

Wong SL, Balch CM, Hurley P, Agarwala SS, Akhurst TJ, Cochran A, Cormier JN, Gorman M, Kim TY, McMasters KM, Noyes RD, Schuchter LM, Valsecchi ME, Weaver DL, Lyman GH. Sentinel lymph node biopsy for melanoma: American Society of Clinical Oncology and Society of Surgical Oncology joint clinical practice guideline. *J Clin Oncol*. 2012 Aug 10;30(23):2912-8. [98 references] [PubMed](#)

Wong SL, Morton DL, Thompson JF, Gershenwald JE, Leong SP, Reintgen DS, Gutman H, Sabel MS, Carlson GW, McMasters KM, Tyler DS, Goydos JS, Eggermont AM, Nieweg OE, Cosimi AB, Riker AI, G Coit D. Melanoma patients with positive sentinel nodes who did not undergo completion lymphadenectomy: a multi-institutional study. *Ann Surg Oncol*. 2006 Jun;13(6):809-16. [PubMed](#)

## Type of Evidence Supporting the Recommendations

The recommendations are partially supported by existing guidance and multi-institutional studies.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Appropriate sentinel node biopsy in primary cutaneous melanoma

### Potential Harms

False-negative sentinel node biopsy results

## Contraindications

### Contraindications

The contraindications for sentinel node biopsy (SLNB) are as follows:

- Absolute contraindications: Clinically positive (N1) axillary lymphadenopathy and positive fine-needle aspiration cytology and/or core biopsy of palpable lymph nodes.
- Relative contraindications (due to the disruption of the lymphatics): Prior wide excision of the primary tumour with rotation flap, prior extensive surgery (e.g., dissection of the neck), previous radiation to the head and the neck, allergy to blue dye and radiocolloid. While SLNB is not contraindicated in pregnancy, it should be noted that vital dyes have not been proven safe for use during pregnancy. Radiocolloid should be used alone if SLNB is undertaken.

## Qualifying Statements

### Qualifying Statements

The recommendations contained in this guideline are a consensus of the Alberta Provincial Cutaneous Tumour Team and are a synthesis of currently accepted approaches to management, derived from a review of relevant scientific literature. Clinicians applying these guidelines should, in consultation with the patient, use independent medical judgment in the context of individual clinical circumstances to direct care.



# Implementation of the Guideline

## Description of Implementation Strategy

- Present the guideline at the local and provincial tumour team meetings and weekly rounds.
- Post the guideline on the Alberta Health Services website.
- Send an electronic notification of the new guideline to all members of CancerControl Alberta.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness

### IOM Domain

Effectiveness

## Identifying Information and Availability

### Bibliographic Source(s)

Alberta Provincial Cutaneous Tumour Team. Sentinel node biopsy in primary cutaneous melanoma. Edmonton (Alberta): CancerControl Alberta; 2014 Feb. 13 p. (Clinical practice guideline; no. CU-011). [75 references]

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2011 Feb (revised 2014 Feb)

### Guideline Developer(s)

CancerControl Alberta - State/Local Government Agency [Non-U.S.]

### Source(s) of Funding

CancerControl Alberta

There was no direct industry involvement in the development or dissemination of this guideline.

# Guideline Committee

Alberta Provincial Cutaneous Tumour Team

## Composition of Group That Authored the Guideline

Members of the Alberta Provincial Cutaneous Tumour Team include medical oncologists, radiation oncologists, surgical oncologists, dermatologists, nurses, pathologists, and pharmacists.

## Financial Disclosures/Conflicts of Interest

Participation of members of the Alberta Provincial Cutaneous Tumour Team in the development of this guideline has been voluntary and the authors have not been remunerated for their contributions. CancerControl Alberta recognizes that although industry support of research, education and other areas is necessary in order to advance patient care, such support may lead to potential conflicts of interest. Some members of the Alberta Provincial Cutaneous Tumour Team are involved in research funded by industry or have other such potential conflicts of interest. However the developers of this guideline are satisfied it was developed in an unbiased manner.

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Alberta Cutaneous Tumour Team. Regional node dissection in primary cutaneous melanoma. Edmonton (Alberta): Alberta Health Services, Cancer Care; 2011 Feb. 11 p. (Clinical practice guideline; no. CU-011). [59 references]

## Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the [Alberta Health Services Web site](#) .

## Availability of Companion Documents

The following is available:

- Guideline utilization resource unit handbook. Edmonton (Alberta): CancerControl Alberta; 2013 Jan. 5 p. Electronic copies: Available in Portable Document Format (PDF) from the [Alberta Health Services Web site](#) .

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on February 10, 2012. The information was verified by the guideline developer on March 30, 2012. This summary was updated by ECRI Institute on April 28, 2014. The updated information was verified by the guideline developer on June 6, 2014.

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